

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**201023**

**CHEMISTRY REVIEW(S)**

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

|                                |  |   |   |
|--------------------------------|--|---|---|
| <b>Application:</b>            | NDA 201023/000   | <b>Action Goal:</b>                                       |   |
| <b>Stamp Date:</b>             | 31-MAR-2010  | <b>District Goal:</b>                                     | 24-MAY-2010   |
| <b>Receipt Date:</b>           | 30-SEP-2010  |   |   |
| <b>Applicant:</b>              | SANOVI AVENTIS SPA<br>55 CORORATE DR<br>BRIDGEWATER, NJ 08807  | <b>Brand Name:</b>  | CABAZITAXEL (XRP6258)                               |
|                                |  | <b>Estab. Name:</b>                                       |   |
|                                |  | <b>Generic Name:</b>                                      |   |
| <b>Priority:</b>               | 1  | <b>Product Number; Dosage Form; Ingredient; Strengths</b> |   |
| <b>Org. Code:</b>              | 150  |   | 001; SOLUTION, CONCENTRATE; CABAZITAXEL; 60MG/1.5ML |
| <b>Application Comment:</b>    | PRIORITY PROSTATE CANCER NDA WITH SHORTENED REVIEW CLOCK- 8 WEEK REVIEW CLOCK. REQUEST COMPLIANCE OVERALL RECOMMENDATION BY 5/24/10 (on 08-APR-2010 by D. MESMER (HFD-800) 301-796-4023) |   |   |
| <b>FDA Contacts:</b>           | D. MESMER  | Project Manager   | (HFD-800) 301-796-4023                              |
|                                | X. CHEN  | Review Chemist  | 301-796-1337  |
|                                | H. SARKER  | Team Leader   | (HFD-150) 301-796-1747                              |
| <b>Overall Recommendation:</b> | ACCEPTABLE   | on 03-MAY-2010 by M. STOCK                                | (HFD-320) 301-796-4753                              |

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

Establishment: CFN: FEI: (b) (4)  
 (b) (4)  
 (b) (4)  
 DMF No: AADA:  
 Responsibilities: (b) (4)  
 Etab. Comment: (b) (4)  
 Profile: OAI Status: NONE

| <u>Milestone Name</u> | <u>Milestone Date</u> | <u>Request Type</u> | <u>Planned Completion</u> | <u>Decision</u>                    | <u>Creator</u> |
|-----------------------|-----------------------|---------------------|---------------------------|------------------------------------|----------------|
| <u>Comment</u>        |                       |                     |                           | <u>Reason</u>                      |                |
| SUBMITTED TO OC       | 08-APR-2010           |                     |                           |                                    | MESMERD        |
| OC RECOMMENDATION     | 21-APR-2010           |                     |                           | ACCEPTABLE<br>BASED ON FILE REVIEW | STOCKM         |

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

**Establishment:** CFN: 9610119 FEI: 3002808000  
AVENTIS PHARMA LTD.

9 QUAI JULES GUESDE  
VITRY-SUR-SEINE, , FRANCE

**DMF No:** (b) (4) **AADA:**

**Responsibilities:** DRUG SUBSTANCE LABELER  
DRUG SUBSTANCE MANUFACTURER  
DRUG SUBSTANCE PACKAGER  
DRUG SUBSTANCE RELEASE TESTER  
DRUG SUBSTANCE STERILITY TESTER

**Estab. Comment:** EMAIL FROM ELIZABETH PHILPY ON 4/7/10 INSTRUCTS THAT INFORMATION SUBMITTED FOR BOTH SANOFI-AVENTIS RECHERCHE & DÉVELOPPEMENT AT 13 QUAI JULES GUESDE AND SANOFI CHIMIE AT 9 QUAI JULES GUESDE SHOULD BE SUBMITTED UNDER THIS FEI NUMBER, 3002808000. SPONSOR INDICATES AT #13 QUAI JULES GUESDE: MANUFACTURING OF THE DRUG SUBSTANCE FROM (b) (4) AND (b) (4) AND MICROBIAL CONTAMINATION TESTING OF THE DRUG SUBSTANCE AT 9 QUAI JULES GUESDE: TESTING AND RELEASE OF (b) (4) TESTING AND RELEASE, PACKAGING AND LABELING OF THE DRUG SUBSTANCE. CONTACT NAME FOR #13 IS :MARIE-PIERRE IMBERT QUALITY ASSURANCE MANAGER MARIE-PIERRE.IMBERT@SANOFI-AVENTIS.COM TEL: 33.1.58.93.88.66 FAX: 33.1.58.93.30.61 (on 07-APR-2010 by D. MESMER (HFD-800) 301-796-4023) PLEASE REFER TO FACTS ASSIGNMENT IDS 1157497 AND 1157501, WHICH WERE ISSUED FOR THIS PRODUCT PRIOR TO SUBMISSION DUE TO THE EXPEDITED STATUS OF THE APPLICATION. (on 09-APR-2010 by M. STOCK (HFD-320) 301-796-4753)

**Profile:** NON-STERILE BULK BY CHEMICAL SYNTHESIS **OAI Status:** NONE

| <u>Milestone Name</u>   | <u>Milestone Date</u> | <u>Request Type</u> | <u>Planned Completion</u> | <u>Decision</u>                       | <u>Creator</u> |
|---|-----------------------|---------------------|---------------------------|---------------------------------------|----------------|
| <u>Comment</u>  |                       |                     |                           | <u>Reason</u>                         |                |
| SUBMITTED TO OC   | 08-APR-2010           |                     |                           |                                       | MESMERD        |
| SUBMITTED TO DO   | 09-APR-2010           | Product Specific    |                           |                                       | STOCKM         |
| ASSIGNED INSPECTION TO IB   | 16-APR-2010           | Product Specific    |                           |                                       | JOHNSONE       |
| DO RECOMMENDATION<br>EXPEDITED COMPLIANCE REVIEW DONE BY DOUG CAMPBELL. | 03-MAY-2010           |                     |                           | ACCEPTABLE<br>INSPECTION              | STOCKM         |
| OC RECOMMENDATION   | 03-MAY-2010           |                     |                           | ACCEPTABLE<br>DISTRICT RECOMMENDATION | STOCKM         |

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

**Establishment:** CFN: 9610433 FEI: 1000541557  
 AVENTIS PHARMA LTD.  
 RAINHAM ROAD SOUTH  
 DAGENHAM, , UNITED KINGDOM

**DMF No:** **AADA:**

**Responsibilities:** FINISHED DOSAGE MANUFACTURER

**Estab. Comment:** MANUFACTURING, TESTING AND RELEASE, PACKAGING AND LABELING OF THE DRUG PRODUCTS (CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION AND SOLVENT FOR DILUTION) (on 07-APR-2010 by D. MESMER (HFD-800) 301-796-4023)

**Profile:** STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS **OAI Status:** NONE

| <u>Milestone Name</u> | <u>Milestone Date</u> | <u>Request Type</u> | <u>Planned Completion</u> | <u>Decision</u>   | <u>Creator</u> |
|-----------------------|-----------------------|---------------------|---------------------------|---|----------------|
| <u>Comment</u>        |                       |                     |                           | <u>Reason</u>   |                |
| SUBMITTED TO OC       | 08-APR-2010           |                     |                           |   | MESMERD        |
| SUBMITTED TO DO       | 08-APR-2010           | 10-Day Letter       |                           |   | STOCKM         |
| DO RECOMMENDATION     | 16-APR-2010           |                     |                           | ACCEPTABLE<br>BASED ON FILE REVIEW                        | JOHNSONE       |
| OC RECOMMENDATION     | 18-APR-2010           |                     |                           | ACCEPTABLE<br>BASED ON PROFILE<br>DISTRICT RECOMMENDATION | INYARDA        |

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